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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,632	08/15/2001	Stephen C. Suffin	10701-010-999	2479
20583	7590	07/02/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			MEINECKE DIAZ, SUSANNA M	
			ART UNIT	PAPER NUMBER

3623

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/930,632

Applicant(s)

SUFFIN ET AL.

Examiner

Susanna-M. Diaz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/15/01, 4/7/03, 9/8/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 9-19 are presented for examination.

Claim Objections

2. Claims 18 and 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-17 and 19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

- (1) whether the invention is within the technological arts; and
- (2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory

subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

While claims 1-17 and 19 recite the useful, concrete, and tangible result of predicting the likelihood of response of a patient to a medication, these claims do not apply, involve, use, or advance the technological arts, and are therefore deemed to be non-statutory.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 9-17 and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the article "Neurometric Subgroups in Attentional and Affective Disorders and Their Association with Pharmacotherapeutic Outcome," written by the inventors (Stephen C. Suffin and W. Hamlin Emory).

7. Claims 9-17 and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the transcript of the presentation "Neurometric EEG Classifiers and Medication Response in DSM Disorders," given by the inventors (Stephen C. Suffin and W. Hamlin Emory).

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8. Claims 9-17 and 19 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. Please refer to the following references which support the Examiner's assertion of public use:

(a) the article "Neurometric Subgroups in Attentional and Affective Disorders and Their Association with Pharmacotherapeutic Outcome," written by the inventors (Stephen C. Suffin and W. Hamlin Emory).

(b) the transcript of the presentation "Neurometric EEG Classifiers and Medication Response in DSM Disorders," given by the inventors (Stephen C. Suffin and W. Hamlin Emory).

(c) the summary of a trial study entitled "Neurometric EEG Predicts Pharmacotherapeutic Outcome in Depressed Outpatients: A Prospective Trial," conducted, in part, by the inventors (Stephen C. Suffin and W. Hamlin Emory).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over the article "Neurometric Subgroups in Attentional and Affective Disorders and Their Association with Pharmacotherapeutic Outcome," written by the inventors (Stephen C. Suffin and W. Hamlin Emory), in view of Itil et al. (U.S. Patent No. 5,730,146).

As discussed above in the rejection of claims 1-17 and 19 over the article "Neurometric Subgroups in Attentional and Affective Disorders and Their Association with Pharmacotherapeutic Outcome," the generic methodology of claim 18 is clearly anticipated by said reference. However, this reference fails to explicitly discuss the incorporation of the method recited in claims 1-17 and 19 in a remote processing environment.

Itil et al., on the other hand, disclose a system for transmitting EEG data and associated patient identifying information via telephone lines from a remote site to a report processing center, along with the electronic return of a report summarizing results of analyses and database comparison (Fig. 5; col. 1, line 62 through col. 2, line 33; col. 9, lines 47-53; col. 11, lines 23-32). Therefore, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to incorporate Itil et al.'s system for transmitting EEG data and associated patient identifying information via telephone lines from a remote site to a report processing center (along with the electronic return of a report summarizing results of analyses and database comparison) with the method for treating psychiatric disorders disclosed in claims 1-17 and 19 as well as in the article "Neurometric Subgroups in Attentional and Affective Disorders and Their Association with Pharmacotherapeutic Outcome" in order to reduce the cost of analyzing EEG and related treatment data on a global scale. In other words, instead of purchasing expensive equipment used for analyzing EEG results for every location where EEG measurements are taken, it would be less

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expensive to centralize access to one set of analyzing equipment at a single reporting center for several remote EEG measurement locations.

11. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over the transcript of the presentation "Neurometric EEG Classifiers and Medication Response in DSM Disorders," given by the inventors (Stephen C. Suffin and W. Hamlin Emory), in view of Itil et al. (U.S. Patent No. 5,730,146).

As discussed above in the rejection of claims 1-17 and 19 over the transcript of the presentation "Neurometric EEG Classifiers and Medication Response in DSM Disorders," the generic methodology of claim 18 is clearly anticipated by said reference. However, this reference fails to explicitly discuss the incorporation of the method recited in claims 1-17 and 19 in a remote processing environment.

Itil et al., on the other hand, disclose a system for transmitting EEG data and associated patient identifying information via telephone lines from a remote site to a report processing center, along with the electronic return of a report summarizing results of analyses and database comparison (Fig. 5; col. 1, line 62 through col. 2, line 33; col. 9, lines 47-53; col. 11, lines 23-32). Therefore, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to incorporate Itil et al.'s system for transmitting EEG data and associated patient identifying information via telephone lines from a remote site to a report processing center (along with the electronic return of a report summarizing results of analyses and database comparison) with the method for treating psychiatric disorders disclosed in

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claims 1-17 and 19 as well as in the transcript of the presentation "Neurometric EEG Classifiers and Medication Response in DSM Disorders" in order to reduce the cost of analyzing EEG and related treatment data on a global scale. In other words, instead of purchasing expensive equipment used for analyzing EEG results for every location where EEG measurements are taken, it would be less expensive to centralize access to one set of analyzing equipment at a single reporting center for several remote EEG measurement locations.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susanna M. Diaz whose telephone number is (703) 305-1337. The examiner can normally be reached on Monday-Friday, 9 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tariq Hafiz can be reached on (703) 305-9643.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703)308-1113.

Any response to this action should be mailed to:

**Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450**

or faxed to:

(703)305-7687


[Official communications; including
After Final communications labeled

"Box AF"]

(703)746-7048

[Informal/Draft communications, labeled
"PROPOSED" or "DRAFT"]

Hand delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 22202, 7th floor receptionist.


Susanna M. Diaz
Primary Examiner
Art Unit 3623
June 26, 2004